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(71) Applicant(s)
Nicholas John Mills
Kingsbank Farmhouse, Kingsbank Lane, Beckley,
NEAR RYE, East Sussex, TN31 6RU, United Kingdom

(72) Inventor(s)
Nicholas John Mills

(74) Agent and/or Address for Service
Nicholas John Mills
Kingsbank Farmhouse, Kingsbank Lane, Beckley,
NEAR RYE, East Sussex, TN31 6RU, United Kingdom

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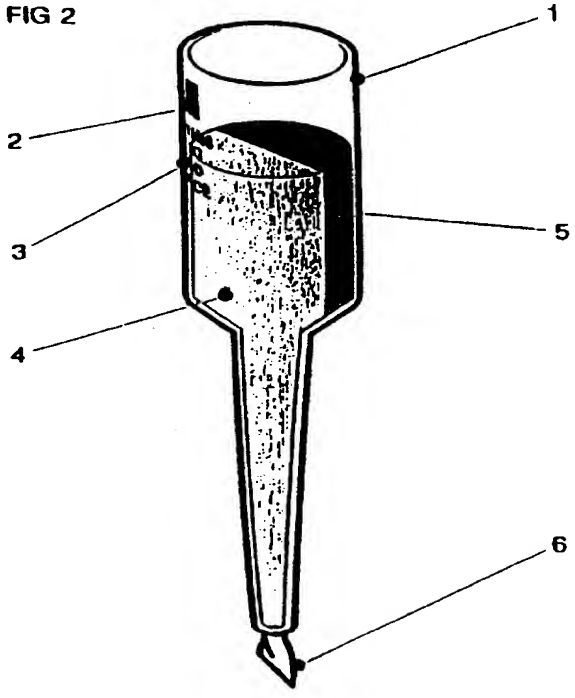
(54) Abstract Title
Wound healing gel application system

(57) The system comprises a flexible container 1 which is to be particularly oriented for use and incorporates an orientation system based on a marker 2 and associated printing 3. The container can be filled with a variety of wound healing gels 4,5 in such a way as to enable a specific, primary gel 4 to be placed on the wound surface with at least one other gel 5 to cover this primary gel layer. The primary gel may contain e.g. pharmaceuticals and local anaesthetics and may include components enabling it to be more easily removed during dressing changes. A combination of suitable gels can be specifically designed for enhancing healing performance.

FIG 2



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The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995

FIG 1

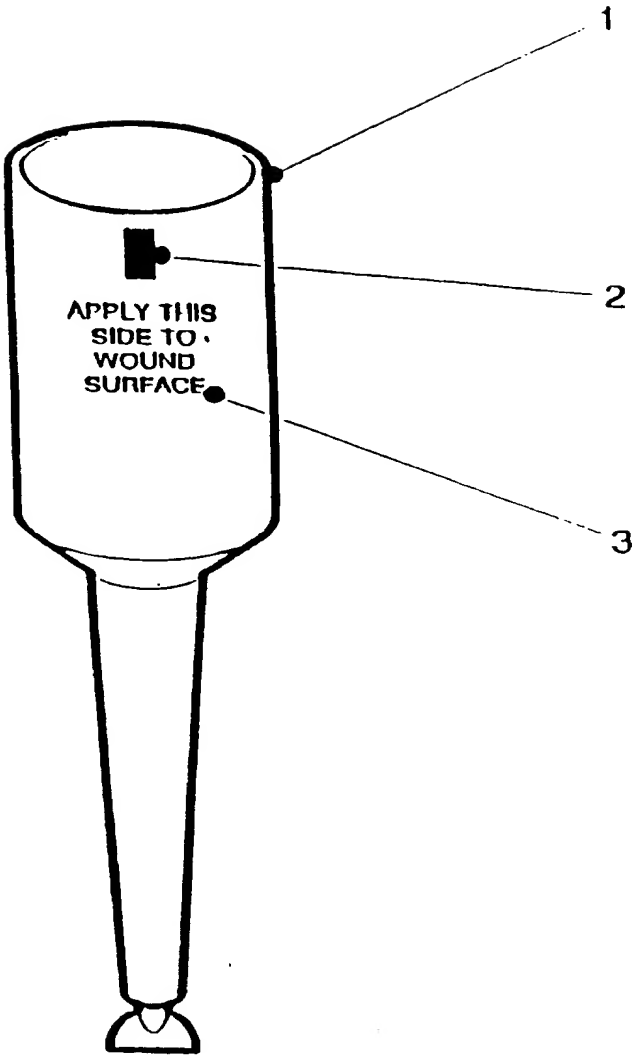


FIG 2

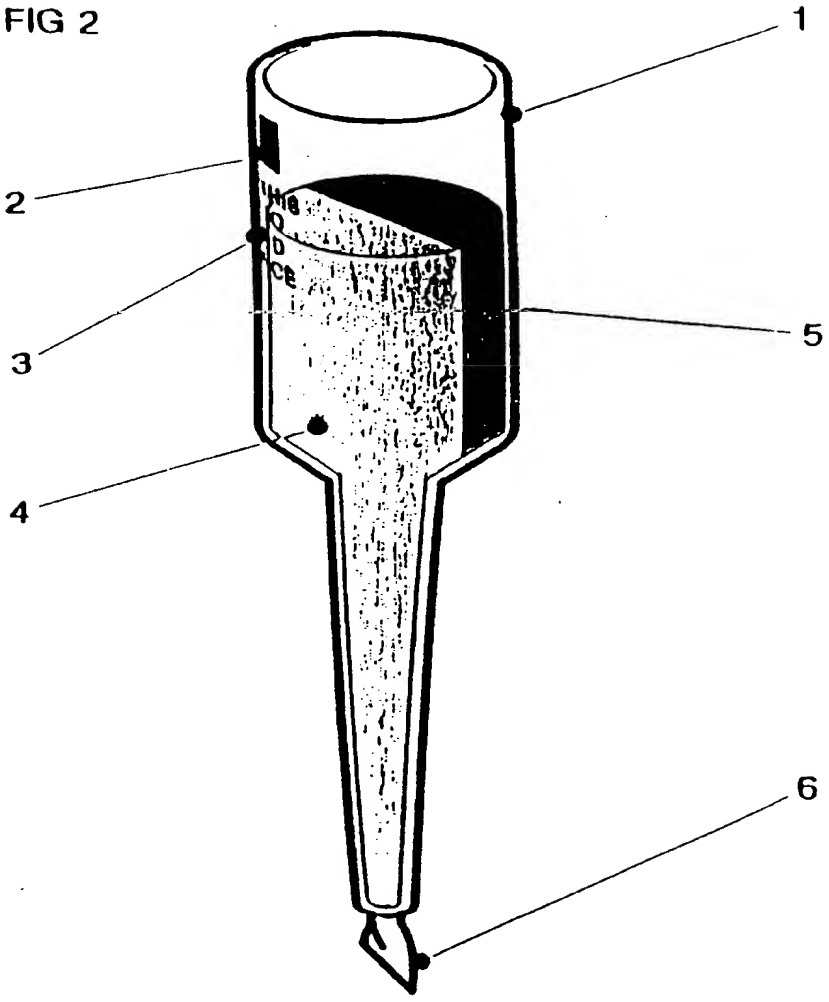


FIG 3

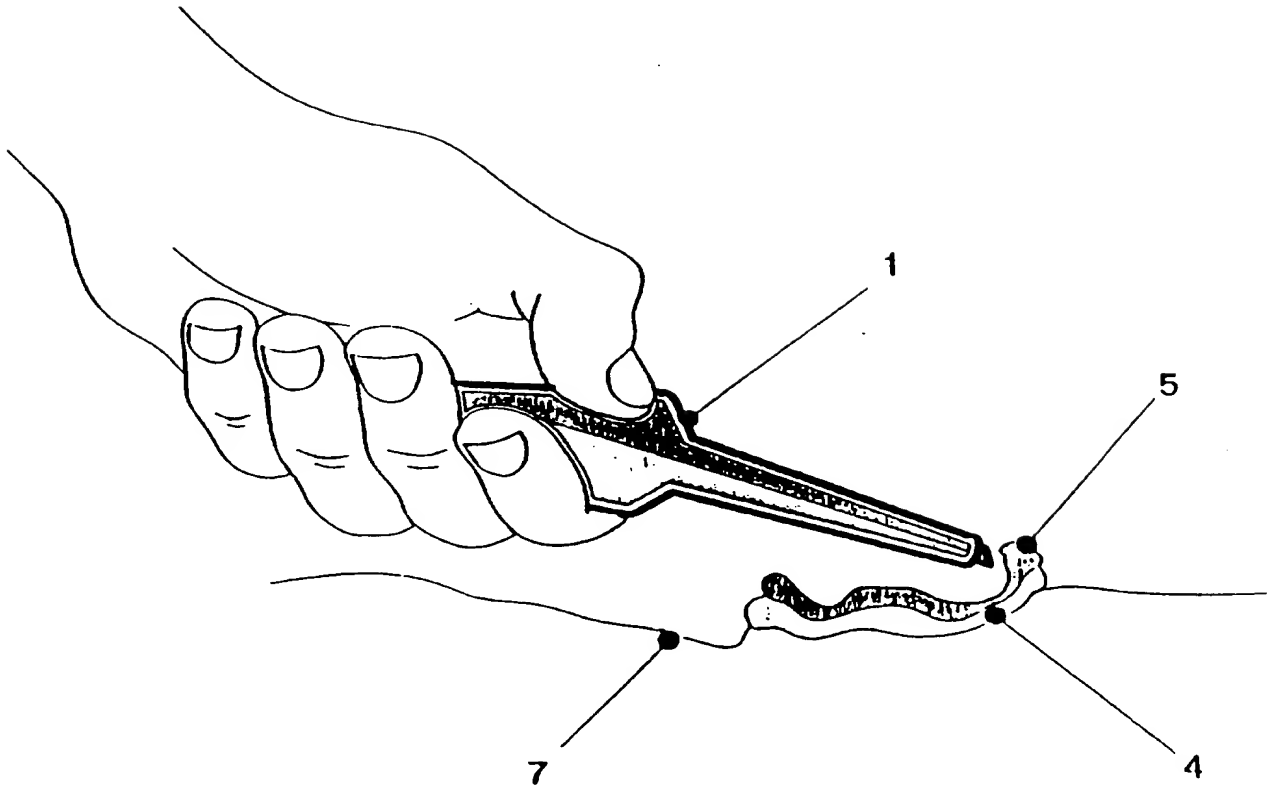


FIG 4

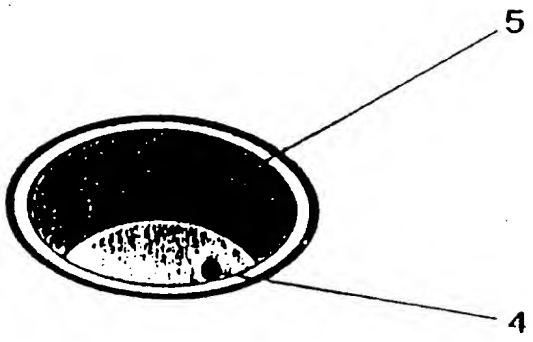
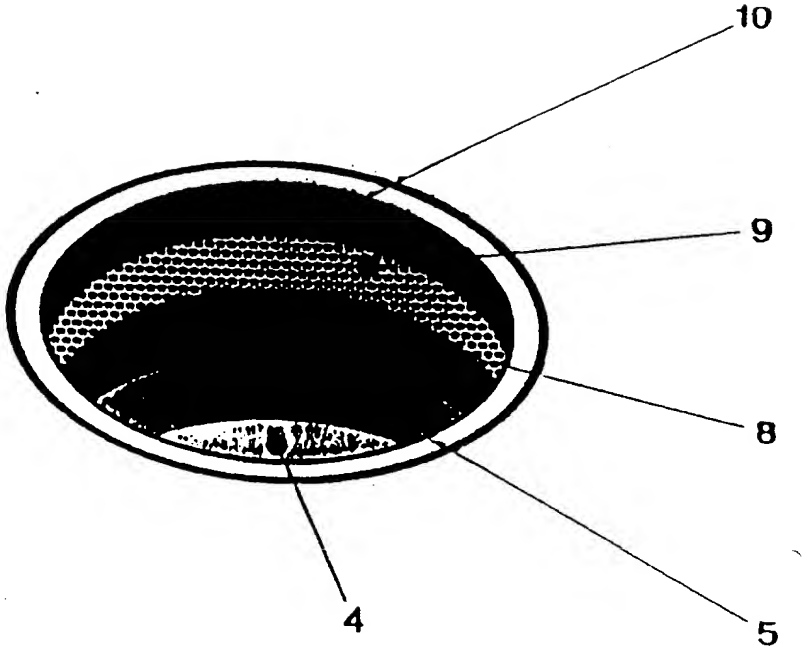


FIG 5



APPLICATOR FOR WOUND HEALING GELS

This invention relates to an applicator for wound healing gels.

In the field of wound care it has been found that a moist wound healing environment is beneficial, that the dressing should absorb or remove excess exudate, provide thermal insulation, prevent contamination and provide an environment which is conducive to the body's natural defence mechanisms.

A well-proven and popular method of producing a moist healing environment for wound healing is to use topical hydrogels as wound dressings. A typical example of such a wound hydrogel is INTRASITE GEL T.M. (Smith & Nephew). Intrasite Gel is a transparent semi-permeable, non adherent hydrogel which is widely used in the human and veterinary fields as a wound dressing. It acts to facilitate and expedite healing by rehydrating necrotic tissue and therefore promoting the natural autolytic process, desloughing and absorption of excess exudate bacteria and toxins.

Intrasite Gel contains a carboxy-methylcellulose polymer, water and propylene glycol. The polymer is only partially hydrated by the water in the gel and therefore retains some

absorptive capacity.

In addition to hydrogels other moist wound healing gels such as calcium alginate gels, collagen gels, sugar gels (e.g. honey) have all been proposed as suitable for wound healing gels.

The various moist wound healing gels have other wound healing benefits. These benefits include an analgesic effect where the wound healing gel has a "soothing effect" by covering the exposed nerve endings within the wound.

Another potential benefit for wound healing gels is to provide a haemostatic effect on the wound surface. The haemostatic effects of calcium alginate and collagen are well documented.

Another potential benefit for wound healing is that it has been demonstrated that a common wound contaminating bacteria - staphylococcus aureus binds to extracellular matrix FIBRONECTIN and collagen (Mamo 1994). It is therefore shown that a wound healing gel containing collagen may be bound to by the wound baceria e.g. staphylococcus aureus such that when for example the collagen gel is removed, by gentle lavage, the numbers of contaminating staphylococcus aureus bacteria are reduced. This type of dressing system has particular significance when dealing with the multiple

antibiotic resistant strains of staphylococcus aureus.

It has also been shown, (Laycock, Platt and Mills 1995) that E. Coli bacteria migrate into a wound hydrogel and are 'bound' into the gel. Thus numbers of contaminating wound bacteria can be significantly reduced when the wound healing gels are "dressing-changed" by lavaging them away from the wound surface.

A further development which may have some significance for wound healing gels is the development of colour-change indicators in the presence of certain bacteria. These colour change indicators have been developed to detect certain bacteria which are important in food poisoning outbreaks but the colour change effect mechanism could also be incorporated to exist in the wound hydrogel at the wound surface. The presence of certain pathogenic bacteria would thus trigger the colour change indicator. The outer layers of the dressing system could be transparent in nature so that the colour change indicator could be readily visualised.

In all the above specialist wound healing gel applications, the wound contact layer of the gel can incorporate features and components which enhance these specific and desirable functions. This "wound contact layer" could then be covered by a further wound hydrogel.

The wound contact gel/hydrogel could e.g. be more fluid, (less viscous) in nature so that it could cover the exposed nerve cells in the wound more effectively increasing the analgesic effect. A secondary gel could cover this wound contact gel layer and be more viscous in nature to keep the wound dressing in place.

The wound contact gel/hydrogel layer could incorporate components such as collagen/fibronectin which would encourage the binding of bacteria such as staphylococcus aureus.

Again such a specialist 'gel' could be held in place by a more viscous secondary gel layer.

For future reference in this patent application, the wound healing gel directly in contact with the wound will be described as the "primary wound contact layer of wound healing gel" or "primary gel layer", with the wound healing gel that surrounds this "primary gel layer" being described as the "secondary gel layer".

The "primary gel layer" could be designed and incorporate components that encourage the migration of wound bacteria into the gel. The "secondary gel layer" could incorporate components that 'bind' the wound healing bacteria. Such

components which are felt to 'bind' wound bacteria include activated charcoal, collagen and fibronectin.

The "primary gel layer" could incorporate components which would enable it to be more easily removed from the wound at wound dressing changes. Such components may enable this gel dressing to "slide-off" the wound at a wound dressing change, under the effects of gentle wound lavage without disturbing the delicate healing epithelial cells.

It is a characteristic of many wound hydrogel dressing systems or hydrocolloid wound dressing systems that they can absorb a great deal of water or a great deal of wound exudate/transudate. When these wound healing hydrogels or hydrocolloid gels have absorbed water, wound exudate or wound transudate to their maximum capacity then the wound healing hydrogels or wound healing hydrocolloid gels change from the "gel phase" to a "liquid phase".

This physical change from the "gel" to the "liquid" phase can be utilised to provide an ideal wound dressing change protocol. In this wound dressing change protocol a gentle "mist-like" irrigation of the wound healing gel can be made using sterile isotonic saline at body temperature. The wound healing hydrogels or the wound healing hydrocolloid gels absorb water until they change from the gel phase to the liquid phase. The gentle "mist-like irrigation"

continues until the wound healing gel or the wound healing hydrocolloid gel is removed from the wound and a wound dressing change has therefore been accomplished with the least possible trauma to the delicate healing epithelial cells. A fresh dressing of the wound hydrogel or the wound hydrocolloid can then be applied to the wound.

Certain wound gels e.g. the hydrocolloid gel produced by Innovative Technology, Winsford, Cheshire, can be used in conjunction with a "primary gel layer" which binds well to the wound surface and which itself is bound to strongly by the hydrocolloid gel. This system thus improves the hydrocolloid gel's ability to bind effectively to the wound surface and hence improve its ease of application to the wound.

Such a "primary gel layer" can be designed so that it readily absorbs sterile isotonic saline at body temperature during the wound dressing changes. This "primary gel layer" could then change from the semi-solid "gel phase" to the "liquid phase" so that it can be readily removed from the wound surface in an atraumatic manner without disturbing the delicate wound healing epithelial cells.

It is against this background that according to the present invention there is provided a method of filling a flexible package with two or more types of compatible wound healing

gels, allowing the filling orientation of the flexible package to be arranged in such a way as to direct the designated primary wound healing gel layer to come into contact with the wound surface and also allow the primary wound healing gel to be covered by the secondary layer of wound healing gel.

A specific embodiment of the invention will now be described by way of example with reference to the accompanying drawings.

A typical flexible package is shown in Fig. 1. The flexible package (1) can be orientated for printing using a "magic eye" photo electric mechanism which orientates the tube via the black line printed on the tube (2). Printed directions can be printed on the flexible tube indicating that the flexible package should be aligned to the wound surface. This type of flexible packaging system with the package orientation has been developed by the Norden Pac International AB for use with their filling machines specifically to enable package printing to be co-ordinated with package sealing.

The invention described here utilises the orientation technology specifically for the specialised filling of a flexible package for specially formulated wound healing gels so that one particular "primary wound gel" can be accurately

placed on to the wound surface and itself be covered by a "secondary wound healing gel".

The Norden Pac International AB machines allow the printed flexible packages to be orientated correctly and accurately and then filled with two (or possibly more) wound healing gels. The printed directions on the flexible pack can instruct the doctor, nurse, veterinary surgeon, dentist etc. to apply the flexible pack orientated correctly towards the wound surface. The designated primary wound gel can then come in contact with the wound surface and itself be covered by the secondary wound gel.

Norden Pac International AB have developed a design of 'filling nozzles' which enable these wound gels to be placed into the flexible package in the required percentage amounts, e.g. the primary wound contact gel could be say 40% and the secondary wound gel could be say 60% of the total. The percentage totals are fully flexible and can be varied to suit specific requirements of wound types etc.

This invention can also be applied to the specially designed applicator for Intrasite Gel, known as the "Applipak".

The empty applipak can be configured for a printing process

on the container which can direct the user to align a specific side of the applipak nearest to the wound surface.

The now printed "applipak" can then, in a separate process be configured, using a "magic eye" photoelectric cell mechanism to enable the applipak to be accurately fitted with two or more wound healing gel types. A specific wound healing gel can thus be fitted on to the side of applipak closest to the wound surface.

The applipak could thus be aligned by the user towards the wound surface and the wound healing gels could thus be applied to the wound in a controlled manner. The existing applipak system could thus be enhanced in its wound healing efficacy by enabling specially designed hydrogels for contact with the wound surface to be accurately applied and these wound surface hydrogels could themselves be covered by another or several other wound hydrogels.

In considering the applipak wound gel dispenser the "bowl" of the applipak is filled with the wound healing gel and then the "shoulder and nozzle" of the applipak are sealed to the "bowl".

It is possible for the applipak bowl to be subdivided by a collapsible wall, or by several collapsible walls, so that the various gels would be separated from one another.

When the nozzle of the applipak is broken off and pressure is applied to the bowl of the applipak (normally by the nurse's thumb), the separating walls would collapse or tear under pressure and the configured hydrogels would then come out of the nozzle and into contact with one another.

This design would enable certain drugs, active molecules, local anaesthetic agents etc. to be delivered to the surface of the wound or surface of the skin and these specific drugs, active molecules or local anaesthetic agents could then be covered by a secondary wound hydrogel. This secondary wound hydrogel could be fairly viscous and hold the active molecule, drug or local anaesthetic agent in place.

A specific embodiment of the invention will now be described by way of example with reference to the accompanying drawing in which:-

Figure 1 shows in perspective an example of a typical empty flexible container 1, on which is a printed "magic eye" alignment mark 2 with aligned printing 3.

Figure 2 shows a cut-away drawing of the filled flexible container 1, showing the primary wound contact gel 4, and the secondary wound healing gel 5.

Figure 2 shows the gel designed to be placed next to the wound surface (4) to be filled into the nozzle of the flexible gel applicator. In practical terms this can be achieved by using a "needle" filling device of the Norden gel filling machine. This needle filler could fill the gel (4) up to the "shoulder" of the flexible gel applicator tube and then a specially designed filler nozzle could be used to fill the main body of the flexible container with both gels (4) and (5). When such a gel is applied to the wound surface the gel which first comes out of the nozzle on to the wound surface (4) is followed by the gel (4) in the main body of the flexible applicator and then by the secondary gel (5).

Figure 3 shows the flexible container 1, with the twist off tab 6, removed from the container and with the benefit of the aligned printing 3 enabling the application of the primary wound healing gel 4, directly on to the wound surface,7. The secondary wound healing gel 5 covers the primary wound healing gel 4.

Figure 4 shows a cross-section of the nozzle with the twist off tab 6, removed. This shows the cross-section of the two types of wound healing gel 4 and 5.

Figure 5 shows an enlarged nozzle with a further

cross-section of the nozzle of the flexible container 1, with the twist off tab 6, removed. This shows a further number of wound healing gel types so that if desirable a 'graded' system of wound healing gels, 8,9,10 could be used to fill a flexible container 1.

CLAIMS

1. A wound healing gel application system in which a flexible container incorporates an orientation system based on a photo-electric marker and orientated printing. This flexible container can be filled with a variety of wound healing gels in an accurate, configured way to enable a specific type of wound healing gel to be placed at the wound surface as the primary gel layer with another or several other wound healing gel(s) to cover this primary gel layer.
2. A wound healing gel applicator as claimed in claim 1 wherein the flexible container is first of all filled with a primary gel layer in the nozzle of the flexible container and then the remainder of the container is filled with a further hydrogel or hydrogels.
3. The primary gel layer as claimed in claim 1 or claim 2 can incorporate specific active pharmaceutical drugs which are active at the wound surface.
4. The pharmaceutical drugs as described in claim 3 can be designed to be activated by laser light as part of a photo dynamic therapy system.
5. A wound healing gel application system as herein described and illustrated in the accompanying drawings.

The Patent Office

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Application No: GB 9718310.7 **Examiner:** L.V.Thomas
Claims searched: 1-5 **Date of search:** 9 June 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5R (RCN, RCX); B8D (DFB, DFX)

Int Cl (Ed.6): A61L 15/00; A61M 35/00; B65D 35/00, 35/24

Other: Online: WPI, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	EP 0243321 A2 (BIOTECH) see p.1 ll.1-15 and p.5 ll.16-24	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.